

510(k) SUMMARY**JUN 26 1996****I. ADMINISTRATIVE**

Submitter: MPM Medical, Inc.
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Contact Person: Paul Miller

Date of Preparation: June 21, 1996

II. DEVICE NAME

Proprietary Name: MPM Hydrogel™ Dressing (Non-Sterile)

Common Name: Wound Dressing

Classification Name: Hydrogel wound and burn dressing

III. PREDICATE DEVICES

1. MPM GelPad (MPM Medical, Inc.); K933495
2. MPM Sterile Hydrogel Dressing in pre-filled syringes (MPM Medical, Inc.); K950934
3. MPM Sterile Hydrogel Dressing in plastic bottles and tubes (MPM Medical, Inc.); K952276
4. MPM Hydrogel Saturated Dressing (MPM Medical, Inc), K930560

IV. DEVICE DESCRIPTION

The MPM Hydrogel Dressing is a clear, viscous, non-sterile, hydrogel intended for use in the local management of skin wounds. The product is supplied in 4 oz. tubes, 8 oz. spray bottles, and 0.5 oz. and 1.0 oz. syringes and meets USP requirements for Antimicrobial Preservative Effectiveness.

V. INTENDED USE

Local management of skin wounds, including pressure ulcers, Stage I-IV, stasis ulcers, first and second degree burns.

VI. COMPARISON TO PREDICATE DEVICES

The MPM Hydrogel Dressing is similar in composition, function and intended use to the MPM GelPad (K933495) and the MPM Sterile Hydrogel Dressing (K950934 and K952276). The only difference between these products is that the hydrogel formulation has been suitably preserved in lieu of terminal sterilization. In addition, the MPM Hydrogel Dressing is similar to the MPM Saturated Hydrogel Dressing which is also supplied non-sterile.

A cytotoxicity test (USP Agarose Diffusion) performed with the MPM Hydrogel Dressing showed the product to be non-cytotoxic with a reactivity profile similar to that of the MPM GelPad and the MPM Sterile Hydrogel Dressing. Since the composition of the two hydrogels is otherwise identical, biocompatibility data submitted for the MPM GelPad (K933495) remain applicable, and no additional biocompatibility tests have been performed with the product.

Accordingly, MPM Medical, Inc. concluded that the MPM Hydrogel Dressing is as safe and effective for its intended use and performs at least as well as legally marketed predicate devices, such as the MPM GelPad, MPM Sterile Hydrogel Dressing and MPM Saturated Hydrogel Dressing.